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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,073	12/19/2006	Frank Plummer	030841-054132-US	2731
50607	7590	03/16/2009		
RONALD I. EISENSTEIN 100 SUMMER STREET NIXON PEABODY LLP BOSTON, MA 02110			EXAMINER HUMPHREY, LOUISE WANG ZHIYING	
			ART UNIT 1648	PAPER NUMBER
			MAIL DATE 03/16/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/555,073	<b>Applicant(s)</b> PLUMMER ET AL.	
	<b>Examiner</b> LOUISE HUMPHREY	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 68-133 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 68-133 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is in response to the preliminary amendment filed on 28 October 2005. Claims 1-67 have been cancelled. Claims 68-133 have been added and are pending.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 68-81, 105-114, 121, 122, and 129 -131, drawn to the special technical feature of a substantially pure SARS virus nucleic acid molecule; a vector comprising the nucleic acid; a host cell comprising the vector; a nucleic acid that hybridizes with or is complementary to a SARS virus nucleic acid and a kit comprising the nucleic acid; a nucleic acid comprising a SARS-antisense sequence; a microarray comprising a plurality of the SARS virus nucleic acids; and a vaccine comprising the SARS nucleic acid.

Group II, claims 82-104, 129 and 131, drawn to the special technical feature of a substantially pure SARS virus polypeptide; a microarray comprising a plurality of the SARS virus polypeptides; and a vaccine comprising a SARS virus polypeptide.

Group III, claims 115, 116, and 122, drawn to the special technical feature of an antibody that specifically binds to a SARS virus polypeptide; a microarray comprising a plurality of the antibodies; and a kit comprising the antibody.

Group IV, claim 117, drawn to the special technical feature of a method for detecting a SARS virus comprising contacting a sample with an antibody that specifically binds a SARS virus polypeptide.

Group V, claims 118 and 119, drawn to the special technical feature of a method for detecting a SARS virus comprising contacting a sample with a hybridizing primer.

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Group VI, claim 120, drawn to the special technical feature of targeting a protein for secretion from a cell, comprising attaching a SARS signal sequence to the protein to be secreted.

Group VII, claims 123-127, drawn to the special technical feature of a method comprising administering a SARS virus polypeptide or fragment thereof to an animal.

Group VIII, claims 123-127, drawn to the special technical feature of a method comprising administering a SARS virus nucleic acid to an animal.

Group IX, claims 126 and 127, drawn to the special technical feature of a method for treating or preventing a SARS virus infection comprising administering a compound to an animal.

Group X, claim 128, drawn to the special technical feature of a method for evaluating a compound for treating or preventing a SARS virus infection.

Group XI, claims 132 and 133, drawn to the special technical feature of a computer readable record comprising distinct SARS virus nucleic acid or amino acid sequences.

The inventions listed as Groups I-XV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

As set forth above, each group requires a technical feature that is not required by any of the other groups.

The first common technical feature among these inventions is a SARS virus nucleic acid. Such a product is disclosed in Rota *et al.* (US patent No. 7,220,852, effectively filed 25 April 2003). Therefore, the technical feature is not a contribution over the art, thus, the claimed inventions cannot be said to have unity of invention.

### ***Restriction to Single Sequence Election***

Note that this is not a species election and is separate from a group election.

Claims 68-133 specifically recite multiple nucleic acid or amino acid sequences, which are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. §121. Each SEQ ID NO. is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. §121 and 37 CFR 1.141 *et seq* (See MPEP §803.04). Each sequence is not considered to be a proper member of a Markush group. See M.P.E.P. § 803.02. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. As such, sequences in each of claims 68-133 are not considered to constitute a proper genus/Markush, and are therefore subject to additional restriction.

Furthermore, a search of more than one (1) of the sequences present in these claims presents an undue burden on the Patent and Trademark Office due to the complex nature of the search in terms of computer time needed to perform the search and the subsequent analysis of the search results by the examiner. Each of the SEQ ID NO's is a unique and separately patentable sequence, requiring a non-coextensive search for the prior art.

In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Therefore, applicants must elect ONE sequence, identified by a single SEQ ID NO., which if determined to be patentable,

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would also be patentably distinct from other sequences. Failure to elect a specific sequence will be considered to be non-responsive reply.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LOUISE HUMPHREY whose telephone number is (571)272-5543. The examiner can normally be reached on Mon-Thu, 9:00 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. H./

Examiner, Art Unit 1648

1 March 2009

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648